

CERTIFICATE OF ANALYSIS

STP Prime ES Ampuled Controls Lot Number 24255049 Ref Number 53110 Exp Date 2026-08-29 Date of Manufacture 2024-08-29 UDI# (01)00385480531108(11)240829(17)260829(10)24255049

Level 1 L/N	24242036			Level 2 L/N	24242037
Level 1 Exp Date	2026-08-29		Lev	el 2 Exp Date	2026-08-29
	<u>Spec</u>	Pass/Fail		<u>Spec</u>	Pass/Fail
рН	7.30 - 7.40	Pass	рН	7.55 - 7.60	Pass
Na+ mmol/L	132 - 156	Pass	Na+ mmol/L	110 - 129	Pass
K+ mmol/L	3.2 - 4.0	Pass	K+ mmol/L	5.6 - 6.8	Pass
CI- mmol/L	95 - 114	Pass	CI- mmol/L	76 - 92	Pass
iCa mg/dL	3.96 - 5.72	Pass	iCa mg/dL	6.49 - 8.85	Pass
iMg mg/dL	0.98 - 1.74	Pass	iMg mg/dL	2.44 - 3.66	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

9/30/2024 Date